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Health Alert Network Advisory: Accessing Tecovirimat (TPOXX) for Patients with Monkeypox

Many people with monkeypox have developed complications including proctitis, which can progress to become severe and debilitating, and lesions in anatomical sites that are at risk of scarring or other permanent sequelae. Supportive care, including pain control, is a mainstay of treatment.

Tecovirimat (TPOXX) is an antiviral medication available through the Centers for Disease Control and Prevention (CDC) that is being used to treat monkeypox infection under CDC's Expanded Access Investigational New Drug (IND) protocol. Recently the FDA and CDC simplified this protocol so that treatment with tecovirimat can begin upon obtaining informed consent from the patient. No pre-registration is required, and evaluations can be done by telemedicine. Additional forms must be submitted to CDC after initiating treatment.

Providers are urged to take the necessary steps to prescribe tecovirimat when indicated for patients who have a positive test result.

Background on Tecovirimat

Tecovirimat is an antiviral medication approved by the United States Food and Drug Administration (FDA) for the treatment of smallpox that is now being used to treat monkeypox infection under an Expanded Access Investigational New Drug (IND) protocol from the Centers for Disease Control and Prevention (CDC). It is available for children and adults as an oral capsule and IV formulation. While data are not available on the effectiveness of tecovirimat in treating monkeypox infections in people, animal studies have shown it is effective in treating disease and reducing the risk of death from Orthopoxviruses. Clinical trials in people have shown the drug is safe with only minor side effects.

When to Consider Tecovirimat for Patient Management

Tecovirimat is indicated for patients with a positive test result (or patients for whom specimens have been submitted for testing and have a clinically compatible illness) and have:

- Severe disease that may manifest as hemorrhagic disease, sepsis, or encephalitis
- Lesions in anatomical areas at special risk of scarring or stricture, such as those near or directly involving the eye, mouth, rectum, or urethra
- Complications, such as urethritis and proctitis, particularly with tenesmus, challenges in pain control, or rectal bleeding
- High risk of severe disease such as those who are immunocompromised, pregnant, or breastfeeding, have a history or presence of atopic dermatitis or other active exfoliative skin conditions, and children

How to Access and Prescribe Tecovirimat

Any provider or health care facility or system can prescribe tecovirimat under the CDC's IND protocol, which was recently simplified, including to allow the use of telemedicine for all patient encounters (initial and follow-up visits) if the patient can submit the signed consent form electronically. Tecovirimat is provided at no cost by the federal government, and patients should not be charged for the medicine; however, providers may bill for the encounter. Providers can prescribe for individual patients as needed.

Follow these steps to prescribe tecovirimat for eligible patients:

1. Discuss confirmed case with ADH Outbreak Response and Prevention Branch (Ph: 501-537-8969, Out of Office Hours: 1-800-803-7847, Email: adh.orsnurses@arkansas.gov).

2. Have the patient sign the Informed Consent Form (ICF).

- Email the signed ICF to Arkansas Department of Health (ADH) at ADH.HAI@arkansas.gov. Please indicate the pharmacy (if known) you would like the medication shipped to.

3. Submit the following additional forms to ADH within 3 days of the patient starting medication:

- Patient Intake Form
    i. https://www.cdc.gov/poxvirus/monkeypox/pdf/Attachment-2-Form-A-Patient-Intake-Form.pdf
- FDA Form 1572
    i. This is a provider/facility enrollment form and is not required for each patient. Only one form is required for each provider or facility and once submitted will cover all prescriptions for that provider, or providers within a facility. Providers and facilities can enroll at any time and submit this form in advance of prescribing tecovirimat to patients.
    ii. https://www.cdc.gov/poxvirus/monkeypox/pdf/Tecovirimat-IND-Form-FDA-1572.pdf

5. Submit the following forms to CDC through their ShareFile.

- Clinical Outcome Form
    i. Conduct two follow-up visits, one while patient is on treatment (ideally between days 7 to 14) and another after treatment completion. These can be completed using telemedicine.
    ii. https://www.cdc.gov/poxvirus/monkeypox/pdf/Attachment-2-Form-B-Clinical-Outcome-Form.pdf
- Serious Adverse Events
    i. Report life-threatening or serious adverse events associated with tecovirimat by sending a completed MedWatch form to regaffairs@cdc.gov or upload to the ShareFile within 72 hours.
    ii. https://www.cdc.gov/poxvirus/monkeypox/pdf/MedWatchForm-for-Tpoxx.pdf

Visit CDC's Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox for detailed information about the IND protocol and forms for their patients. https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

Testing is currently available through several large commercial laboratories, including LabCorp, Quest, Aegis, Sonic Healthcare, and Mayo Labs. For providers planning to test through a commercial lab, there is no need to contact ADH prior to testing. For providers needing to test through ADH's Glen F. Baker Public

Health Lab, call ADH's Outbreak Response Section first at 501-537-8969 or 1-800-803-7847. Specimens can be dropped off M-F 8 a.m.-7:30 p.m.. No testing is conducted at the Glen F. Baker Public Health Lab over the weekend. Specimens can be stored at 2-8°C. You can find more information on https://www.healthy.arkansas.gov/programs-services/topics/monkeypox

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